PEPCID COMPLETE- famotidine, calcium carbonate, and magnesium hydroxide tablet, chewable Morning Star OTC

Pepcid [®] Complete

Drug Facts

| Active ingredients (in each chewable tablet) | Purposes |
|--|--------------|
| Famotidine 10 mg | Acid reducer |
| Calcium carbonate 800 mg | Antacid |
| Magnesium hydroxide 165 mg | Antacid |

Use

relieves heartburn associated with acid indigestion and sour stomach

Warnings

Allergy alert

Do not use if you are allergic to famotidine or other acid reducers

Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with lightheadedness, sweating, or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain
- kidney disease

Ask a doctor or pharmacist before use if you are taking a prescription drug. Antacids and acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- adults and children 12 years and over:
 - do not swallow tablet whole: chew completely
 - to relieve symptoms, **chew** 1 tablet before swallowing
 - do not use more than 2 chewable tablets in 24 hours
- children under 12 years: ask a doctor

Other information

- each tablet contains: calcium 320 mg, magnesium 70 mg
- read the directions and warnings before use
- read the bottle. It contains important information.
- store at 20°-25°C (68°-77°F)
- protect from moisture
- do not use if foil inner seal imprinted with "Sealed For Your Safety" is broken or missing

Inactive ingredients

cellulose acetate, corn starch, crospovidone, D&C red no. 7 calcium lake, dextrose excipient, FD&C blue no. 1 aluminum lake, FD&C red no. 40 aluminum lake, flavors, gum arabic, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, maltodextrin, mineral oil, modified starch, sucralose

Questions or comments?

call 1-800-755-4008(toll-free) or 215-273-8755(collect)

Repackaged by:

Morning Star OTC

145 S. Anderson St, Los Angeles,

CA 90033

PRINCIPAL DISPLAY PANEL-1 Tablets



PRINCIPAL DISPLAY PANEL-1 Tablets x 25 Packets



PEPCID COMPLETE

| iamotiume, calcit | uni carbor | nate, and magnes | | lablet, che | ewable | | |
|---|--|----------------------------|-------------------|-----------------|------------------------------|----------|---------|
| Product Infor | mation | | | | | | |
| Product Type | | HUMAN OTC DF | RUG Item Code | (Source) | NDC:53209-4001(NDC:16837-298 | | |
| Route of Admin | istration | ORAL | | | | | |
| | | | | | | | |
| Active Ingredient/Active Moiety Ingredient Name | | | | | Basis of | Stronath | Strongt |
| | | - | | | Basis of Strength | | 10 mg |
| | ALCIUM CARBONATE (UNII: H0G9379FGK) (CARBONATE ION - | | | CALCIUM CA | | 800 mg | |
| | ROXIDE (UN | III: NBZ3QY004S) (H | YDROXIDE ION - | | MAGNESIUM HYDROXIDE | l | 165 mg |
| | | | | | | | |
| Inactive Ingre | dients | | | | | | |
| | | Ingredier | nt Name | | | S | trength |
| CELLULOSE ACET | ATE (UNII: 3 | BJ2P07GVB6) | | | | | |
| STARCH, CORN (U | NII: 08232N | Y3SJ) | | | | | |
| CROSPOVIDONE (| UNII: 25783 | 0E561) | | | | | |
| DEXTROSE, UNSP | ECIFIED FO | ORM (UNII: IY9XDZ 35 | 5W2) | | | | |
| FD&C BLUE NO. 1 | | M LAKE (UNII: J9EQA | 3S2JM) | | | | |
| ALUMINUM OXIDE | (UNII: LMI26 | 606933) | | | | | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | | | | | | | |
| D&C RED NO. 7 (U | INII: ECWOLZ | 241X8) | | | | | |
| ACACIA (UNII: 5C54 | 103N26O) | | | | | | |
| HYDROXYPROPYL | CELLULOS | E, UNSPECIFIED (U | JNII: 9XZ8H6N6OH) | | | | |
| HYPROMELLOSE, | UNSPECIFI | ED (UNII: 3NXW29V3 | WO) | | | | |
| LACTOSE MONOH | YDRATE (U | NII: EWQ57Q8I5X) | | | | | |
| MAGNESIUM STEA | ARATE (UNII: | : 70097M6I30) | | | | | |
| MALTODEXTRIN (U | JNII: 7CVR7L | 4A2D) | | | | | |
| MINERAL OIL (UNII | : T5L8T28F0 | GP) | | | | | |
| SUCRALOSE (UNII: | 96K6UQ3Z1 | D4) | | | | | |
| | | | | | | | |
| Product Chara | acteristi | cs | | | | | |
| Color | | purple | Score | | 1 | no score | |
| Shape | | ROUND | Size | | - | 18mm | |
| Flavor | | BERRY | Imprint Code | | | Р | |
| Contains | | | | | | | |
| Packaging | | | | | | | |
| # Item Code | | | | | ing Start | - | |
| 1 NDC:53209- 4001-2 | 25 in 1 PAC | - | • | D 06/19/2025 | ate | Da | ate |
| 4001-2 | 1 in 1 DUCTED DACK. Type Q. Net a Combination | | | | | | |

NDC:53209-

1 in 1 BLISTER PACK; Type 0: Not a Combination

| 4001-1 | Product | | | |
|-----------------------|---|-------------------------|-----------------------|--|
| | | | | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| NDA | NDA020958 | 06/19/2025 | | |
| | | | | |

Labeler - Morning Star OTC (078589357)

Registrant - Morning Star OTC (078589357)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|----------------------------|
| Morning Star OTC | | 078589357 | repack(53209-4001) |

Revised: 6/2025

Morning Star OTC